

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Edwards et al.
Serial No.: Unknown
Filed: 5 December 2003
For: Sphincter Treatment Apparatus

Mail Stop Patent Application
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

**TRANSMITTAL OF INFORMATION DISCLOSURE STATEMENT WITHIN
THREE MONTHS OF FILING OR BEFORE MAILING OF FIRST OFFICE ACTION
(37 CFR 1.97(b))**

NOTE: "An information disclosure statement shall be considered by the Office if filed: (1) within three months of the filing date of a national application; (2) within three months of the date of entry of the national stage as set forth in S 1.491 in an international application; or (3) before the mailing date of a first Office action on the merits, whichever event occurs last." 37 CFR 1.97(b).

NOTE: The "filing date of a national application" under 37 CFR 1.97(b) has two possible meanings. Where the filing is a direct one to the United States Patent & Trademark Office, the filing is defined in 37 CFR 1.53(b) as "the date on which: (1) A specification containing a description pursuant to S 1.71 and at least one claim pursuant to S 1.75; and (2) any drawing required by S 1.81(a), are filed in the Patent and Trademark Office in the name of the actual inventor or inventors as required by S 1.41." 37 CFR 1.97(b)(1). On the other hand, an international application that enters the national stage occurs when the applicant has filed the documents and fees required by 35 U.S.C. S 371(c) within the periods set forth in S 1.494 or S 1.495. 35 U.S.C. S 371(c) requires the filing of the following: (1) the national fee; (2) a copy of the international application, unless already sent by the International Bureau, and an English translation if filed in another language; (3) amendments under PCT Article 19, with a translation into English if made in another language; (4) an oath or declaration; and (5) a translation into English of any annexes to the international preliminary examination report, if such annexes were made in another language. 37 CFR 1.97(b)(2).

**IDENTIFICATION OF TIME OF FILING THE ACCOMPANYING INFORMATION
DISCLOSURE STATEMENT**

The information disclosure statement submitted herewith is being filed WITHIN THREE MONTHS OF THE FILING DATE OF THE APPLICATION OR DATE OF ENTRY INTO THE NATIONAL STAGE OF AN INTERNATIONAL APPLICATION OR BEFORE THE MAILING DATE OF A FIRST OFFICE ACTION ON THE MERITS, WHICHEVER EVENT OCCURS LAST. 37 CFR 1.97(b).

NOTE: "NO CERTIFICATION OR FEE IS DUE WHEN THE FILING IS MADE WITHIN THE ABOVE TIME PERIOD. IT IS ADVISABLE TO ENSURE THAT NO OFFICE ACTION HAS BEEN MAILED IF THE DISCLOSURE STATEMENT IS DELAYED UNTIL AFTER THREE MONTHS FROM FILING.

NOTE: "An information disclosure statement will be considered to have been filed on the day it was received in the Office, or on an earlier date of a mailing if accompanied by a properly executed certificate of mailing under 37 CFR 1.8, or Express Mail certificate under 37 CFR 1.10. An Office action is mailed on the date indicated in the Office action." Notice of April 20, 1992 (1138 O.G. 37-41, 39).

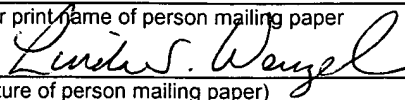
CERTIFICATE OF MAILING (37 CFR 1.8(a)) or (37 CFR 1.10)

I hereby certify that this paper (along with any referred to as being attached or enclosed) is being deposited with the United State Postal Service on the date shown below as Express Mail Label No. EV 317559980 in an envelope addressed as follows: Commissioner for Patents, PO Box 1450, Alexandria, VA 22313-1450

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- NOTE: "The term 'national application' includes continuing applications (continuations, divisions, continuations-in-part) so three-months will be measured from the actual filing date of an application as opposed [sic] to the effective date of a continuing application." Notice of April 20, 1992 (1138 O.G. 37-41, 39).
- NOTE: "An action on the merits means an action which treats the patentability of the claims in an application, as opposed to only formal or procedural requirements. An action on the merits would, for example, contain a rejection or indication of allowability of a claim or claims rather than just a restriction requirements (37 CFR 1.142) or just a requirement for additional fees to have a claim considered (37 CFR 1.16(d)). Thus, if an application was filed on Jan. 1 and the first Office action on the merits was not mailed until six months later on July 1, the examiner would be required to consider any proper information disclosure statement filed prior to July 1." Notice of April 20, 1992 (1138 O.G. 37-41, 39).
- WARNING: "A PETITION FOR SUSPENSION OF ACTION TO ALLOW APPLICANT TIME TO SUBMIT AN INFORMATION DISCLOSURE STATEMENT WILL BE DENIED AS FAILING TO PRESENT GOOD AND SUFFICIENT REASONS, SINCE 37 CFR 1.97 PROVIDES ADEQUATE RECOURSE FOR THE TIMELY SUBMISSION OF PRIOR ART FOR CONSIDERATION BY THE EXAMINER." NOTICE OF JULY 6, 1992 (1141 O.G. 63).

The submission of any document herewith is not intended as an admission that such document constitutes prior art against the claims of the present application or that such document is considered material to patentability as defined in 37 CFR §1.56(b). Applicant does not waive any rights to take any action which would be appropriate to antedate or otherwise remove as a competent reference any document which is determined to be a *prima face* prior art reference against the claims of the present application.

COPIES OF THE DOCUMENTS LISTED ON THE ATTACHED FORM PTO-1449 CAN BE FOUND IN THE FILE WRAPPER OF PARENT APPLICATION SERIAL NO. 09/776,140 FILED 2 FEBRUARY 2001 AND ARE THEREFORE NOT INCLUDED WITH THIS SUBMISSION.

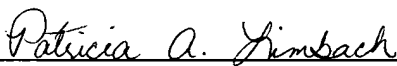
Should any fees be necessary in connection with this submission, please charge same to Account No. 06-2360.

Date 5 December 2003

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LIST OF PRIOR ART CITED BY APPLICANT (Use several sheets if necessary)	ATTY DOCKET NO. 9222.16953-CON DIV	SERIAL NO. Unknown
	APPLICANT Edwards et al.	
	FILING DATE 5 December 2003	GROUP Unknown

U.S. PATENT DOCUMENTS

Examiner Initial	DOCUMENT NUMBER	Date	Name	Class	Subclass	Filing Date (If Appropriate)
	5,957,920	9/28/1999	Baker			
	6,197,022	3/6/2001	Baker			
	5,448,990	9/12/1995	De Faria-Correa			
	6,073,052	6/06/2000	Zelickson et al.			
	4,790,310	12/1998	Ginsburg et al.			
	6,014,579	1/2000	Pomeranz et al.			
	5,395,361	3/1995	Fox et al.			
	6,355,031	3/2002	Edwards et al.			
	6,006,755	12/1999	Edwards			
	6,009,877	1/2000	Edwards			
	6,056,744	5/2000	Edwards			

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		DOCUMENT NUMBER	DATE	COUNTRY	Class	Subclass	Translation Yes No

OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)

EXAMINER	DATE CONSIDERED
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*EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	1,798,902	03/31/1931	Raney			
	3,517,128	06/23/1970	Hines			
	3,901,241	08/26/1975	Allen, Jr.			
	4,011,872	03/15/77	Komiya			
	4,196,724	04/08/1980	Wirt et al.			
	4,411,266	10/25/1983	Cosman			
	4,423,812	01/03/1984	Sato			
	4,532,924	08/06/1985	Auth et al.			
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	4,705,041	11/10/1987	Kim			
	4,901,737	02/20/1990	Toone			

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						YES	NO

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	4,906,203	03/06/1990	Margrave et al.			
	4,907,589	03/13/1990	Cosman			
	4,943,290	07/24/1990	Rexroth et al.			
	4,947,842	08/14/1990	Marchosky et al.			
	4,955,377	09/11/1990	Lennox et al.			
	4,966,597	10/30/1990	Cosman			
	4,976,711	12/11/1990	Parins et al.			
	5,019,075	05/28/1991	Spears et al.			
	5,305,696	07/30/1991	Rydell			
	5,046,512	09/10/1991	Murchie			
	5,047,028	09/10/1991	Qian			

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	5,057,107	10/15/1991	Parins et al.			
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	5,084,044	01/28/1992	Quint			
	5,088,979	02/18/1992	Filipi et al.			
	5,094,233	03/10/1992	Brennan			
	5,100,423	03/31/1992	Fearnot			
	5,106,360	04/21/1992	Ishiwara et al.			
	5,122,137	06/16/1992	Lennox			
	5,125,928	06/30/1992	Parins et al.			
	5,156,151	10/20/1992	Imran			

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	5,190,541	03/02/1993	Abele et al.			
	5,197,963	03/30/1993	Parins			
	5,197,964	03/30/1993	Parins			
	5,205,287	04/27/1993	Erbel et al.			
	5,215,103	06/01/1993	Desai			
	5,232,444	08/03/1993	Just et al.			
	5,236,413	08/17/1993	Fiering			
	5,242,441	09/07/1993	Avitall			
	5,254,126	10/19/1993	Filipi et al.			
	5,256,138	10/26/1993	Vurek et al.			
	5,257,451	11/02/1993	Edwards et al.			

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	5,263,493	11/23/1993	Avitall			
	5,275,162	01/04/1994	Edwards et al.			
	5,275,608	01/04/1994	Forman et al.			
	5,275,610	01/04/1994	Eberbach			
	5,277,201	01/11/1994	Stern			
	5,281,216	01/25/1994	Klicek			
	5,281,217	01/25/1994	Edwards et al.			
	5,281,218	01/25/1994	Imran			
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	5,293,869	03/15/1994	Edwards et al.			

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	5,309,910	05/10/1994	Edwards et al.			
	5,313,943	05/24/1994	Houser et al.			
	5,314,466	05/24/1994	Stern et al.			
	5,316,020	03/31/1994	Truffer			
	5,324,284	06/28/1994	Imran			
	5,328,467	07/12/1994	Edwards et al.			
	5,334,196	08/02/1994	Scott et al.			
	5,336,222	08/09/1994	Durgin, Jr. et al.			
	5,345,936	09/13/1994	Pomeranz et al.			
	5,348,554	09/20/1994	Imran et al.			
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	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
						YES	NO
	0 139 607	5/1985	EPO				
	0 608 609	8/1994	EPO				
	43 03 882	2/1995	Germany				
	38 38 840	2/1997	Germany				
	91/01773	1991	PCT				

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		Castell, D.O. "Gastroesophageal Reflux Disease: Current Strategies for Patient Management." Arch Fam Med. 5(4): 221-7.
		Dallemagne, B. et al., "Laparoscopic Nissen Fundoplication: Preliminary." Surgical Laparoscopy & Endoscopy. 1991 1(3): 138-43

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	5,365,926	11/22/1994	Desai			
	5,365,945	11/22/1994	Halstrom			
	5,366,490	11/22/1994	Edwards et al.			
	5,368,557	11/29/1994	Nita et al.			
	5,368,592	11/29/1994	Stern et al.			
	5,370,675	12/06/1994	Edwards et al.			
	5,370,678	12/06/1994	Edwards et al.			
	5,383,876	01/24/1995	Nardella			
	5,383,917	01/24/1995	Desai et al.			
	5,385,544	01/31/1995	Edwards et al.			
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						YES	NO
	92/10142	1992	PCT				
	93/08755	1993	PCT				
	94/10925	1994	PCT				
	94/21165	1994	PCT				
	94/21178	1994	PCT				

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	Hinder, R.A. et al., "The Technique of Laparoscopic Nissen Fundoplication." Surgical Laparoscopy & Endoscopy. 1992. 2(3): 265-272.
	Karlstrom, L.H. et al. "Ectopic jejunal pacemakers and enterogastric reflux after Roux gastrectomy: Effect of intestinal pacing." Surgery 1989. 106(3): 486-495

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	5,398,683	03/21/1995	Edwards et al.			
	5,401,272	03/28/1995	Perkins			
	5,403,311	04/04/1995	Abele et al.			
	5,409,453	04/25/1995	Lundquist et al.			
	5,409,483	04/25/1995	Campbell et al.			
	5,415,657	05/16/1995	Taymor-Luia			
	5,421,819	06/06/1995	Edwards et al.			
	5,423,808	06/13/1995	Edwards et al.			
	5,423,811	06/13/1995	Ellman et al.			
	5,423,812	06/13/1995	Ellman et al.			
	5,433,739	07/18/1995	Sluijter et al.			

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	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
						YES	NO
	94/22366	1994	PCT				
	94/26178	1994	PCT				
	95/18575	1995	PCT				
	95/19142	1995	PCT				
	95/25472	1995	PCT				

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		Kelly, KA. et al., "Doudenal-gastric reflux and slowed gastric emptying by electrical pacing of the canine duodenal pacesetter potential." Gastroenterology. 1977. 72(3): 429-33
		Reynolds, J.C. "Influence of pathophysiology, severity, and cost on the medical management of gastroesophageal reflux disease." Am J Health-Syst Pharm. 53 (22 Suppl 3): S5-12.

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	5,441,499	08/15/1995	Fritzsche			
	5,443,470	08/22/1995	Stern et al.			
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	5,470,308	11/28/1995	Edwards et al.			
	5,471,982	12/05/1995	Edwards et al.			
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						YES	NO
	96/00042	1996	PCT				
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	96/00042	1996	PCT				
	97/06857	1997	PCT				

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	Urschel, J.D. "Complications of Antireflux Surgery." Am J Surg. 1993. 166(1): 68-70.
	Kaneko, et al., Physiological Laryngeal Pacemaker, May 1985, Trans Am Soc. Artif. Intern Organs, Vol. XXXI, pgs. 293-296

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	5,484,400	01/16/1996	Edwards et al.			
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	5,490,984	02/13/1996	Freed			
	5,496,271	03/05/1996	Burton et al.			
	5,496,311	03/05/1996	Abele et al.			
	5,500,012	03/19/1996	Brucker et al.			
	5,505,728	04/09/1996	Ellman et al.			
	5,505,730	04/09/1996	Edwards			
	5,507,743	04/16/1996	Edwards et al.			
	5,509,419	04/23/1996	Edwards et al.			
	5,514,130	05/07/1996	Baker			

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						YES	NO
	97/32532	1997	PCT				
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Mugica et al. Direct Diaphragm Stimulation, Jan. 1987 PACE, Vol. 10, pgs 252-256

Mugica et al., Neurostimulation: An Overview, Chapter 21, Preliminary Test of a Muscular Diaphragm pacing System on Human Patients. 1985. pgs3. 263-279

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	5,531,676	07/02/1996	Edwards et al.			
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	5,536,240	07/16/1996	Edwards et al.			
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	5,549,644	08/27/1996	Lundquist et al.			
	5,554,110	09/10/1996	Edwards et al.			
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			Rice et al., Endoscopic Paranasal Sinus Surgery, Chapter 5, Functional Endoscopic Paranasal Sinus Surgery, The Technique of Messerklinger, Raven Press, 1988, pgs. 75-104
			Rice et al., Endoscopic Paranasal Sinus Surgery, Chapter 6, Total Endoscopic Sphenoidectomy, The Technique of Wigand, Raven Press, 1988, pgs. 105-125

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